

REMARKS

Kindly note that the correspondence address for the present application has been changed, as indicated in the Change of Attorney or Agent's Address in Application filed on April 24, 2003. A copy of the Change of Attorney or Agent's Address in Application, as filed on April 24, 2003, is attached hereto.

Claims 1-50 are pending in the subject application. Claims 1-20, 35-44, and 47-50 have been withdrawn pursuant to a restriction requirement as being drawn to non-elected inventions, and these claims have been canceled hereinabove. Claims 27, 29-31, and 45 have been withdrawn pursuant to a species election requirement as being drawn to non-elected species, but these claims have not been canceled. Other than the cancellation of claims 1-20, 35-44, and 47-50, no amendments to the claims have been made in this paper. Accordingly, claims 21-26, 28, 32-34, and 46 remain under consideration, and, as discussed below, claims 27, 29-31, and 45 should be placed under consideration. In view of the following remarks, applicants respectfully request reconsideration of the rejections set forth in the outstanding office action and request that claims 27, 29-31, and 45 be considered in this application.

The rejection of claims 21-23 and 32-33 under 35 U.S.C. § 112, first paragraph, for failing to enable one skilled in the art to use the invention commensurate in scope with these claims is respectfully traversed. In this regard, the PTO has taken the position that, while the specification

is enabling for those $\alpha_3\beta_4$ nicotinic receptor antagonists which are specifically disclosed in the specification, it does not enable the use of $\alpha_3\beta_4$ nicotinic receptor antagonists generally. Applicants submit that the data set forth in the specification provides reasonable assurance to one skilled in the art that any combination of two different $\alpha_3\beta_4$ nicotinic receptor antagonists would be useful in the treatment of addiction disorders. More particularly, the present specification presents data showing the effect of six different combinations of four different $\alpha_3\beta_4$ nicotinic receptor antagonists on three different addictions. It is submitted that these data would provide reasonable assurance to one skilled in the art that any combination of two different $\alpha_3\beta_4$ nicotinic receptor antagonists would be useful in the treatment of addiction disorders.

The rejection of claims 21-26, 28, 32-34, and 46 under 35 U.S.C. § 103(a) for obviousness over Glick et al., "18-Methoxycoronaridine, a Non-toxic Iboga Alkaloid Congener: Effects on Morphine and Cocaine Self-administration and on Mesolimbic Dopamine Release in Rats," Brain Res., 719:29-35 (1996) ("Glick") in view of Pulvirenti et al., "Dextromethorphan Reduces Intravenous Cocaine Self-administration in the Rat," Eur. J. Pharmacol., 321:279-283 (1997) ("Pulvirenti") is respectfully traversed.

More particularly, the outstanding office action states that Glick teaches the use of 18-methoxycoronaridine ("18-MC") in the treatment of cocaine addiction and that Pulvirenti teaches the use of dextromethorphan ("DM") to treat of cocaine addiction. The outstanding office action goes on to assert (i) that it would have been obvious to combine two

compositions each of which is taught by prior art to be useful for the same purpose; (ii) that "[t]he combination of active ingredient with the same character is merely the additive effect of each individual component"; and (iii) that the present specification provides no evidence to establish the unexpected or unobvious nature of the claimed invention.

Contrary to the assertion made in the outstanding office action, the present application does indeed establish the unexpected or unobvious nature of the claimed invention.

More particularly, as the outstanding office action indicates, one skilled in the art would have expected that "[t]he combination of active ingredient with the same character . . . [would be] merely the additive effect of each individual component" (emphasis added).

Using this logic and referring to Figure 5 of the present application, the effect of 18-MC vs. baseline is a decrease of about 1 morphine infusion per hour; the effect of DM vs. baseline is a decrease of about 3 morphine infusions per hour; and, if the effect were additive, which, according to the outstanding office action, is what one skilled in the art would have expected, one would expect that the combined use of 18-MC and DM would result in a decrease of about 4 morphine infusions per hour. Instead, as Figure 5 shows, combined use of 18-MC and DM results in a decrease of about 27 morphine infusions per hour (i.e., more than 6.5 times what one would have expected).

Similarly, using the outstanding office action's logic and referring to Figure 11 of the present application, the effect of 18-MC vs. baseline is a decrease of about 4

nicotine infusions per hour; the effect of DM vs. baseline is a decrease of about 2 nicotine infusions per hour; and, if the effect were additive, which, according to the outstanding office action, is what one skilled in the art would have expected, one would expect that the combined use of 18-MC and DM would result in a decrease of about 6 nicotine infusions per hour. Instead, as Figure 11 shows, combined use of 18-MC and DM results in a decrease of about 14 nicotine infusions per hour (i.e., more than 2.3 times what one would have expected).

Thus, the data in the specification demonstrate that the combination of 18-MC and DM produces results which are significantly better than what one skilled in the art would have expected. Accordingly, claims 21-26, 28, 32-34, and 46 should be patentable over the combined teachings of Glick and Pulvirenti.

Further, since the present claims have been subjected to a species election requirement and since the elected species is allowable (for all of the reasons set forth above), applicants respectfully request that the PTO now examine the claims that were withdrawn as being directed to non-elected species (i.e., claims 27, 29-31, and 45).

In view of the foregoing, it is submitted that this case is in condition for allowance, and such allowance is earnestly solicited. Should any issues remain which can usefully be discussed by telephone, the Examiner is invited to contact applicants' undersigned attorney at the number provided below.

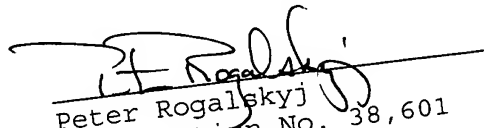
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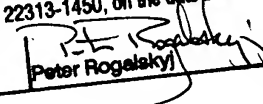
Again, please note that the correspondence address
for the present application has been changed, as discussed
above.

Respectfully submitted,

Dated: January 12, 2004


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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.	
1-12-04 Date	 Peter Rogalskyj